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FEB 26 2004

X. 510(k) SUMMARY

SUBMITTER:	COBE Cardiovascular 14401 W 65th Way Arvada, CO 80004, USA
CONTACT PERSON:	Lynne Leonard E-mail: lynne.leonard@cobecv.com Phone: 303-467-6194 Fax: 303-467-6429
DATE PREPARED:	January 23, 2004
DEVICE TRADE NAME:	Dideco Micro 40 Ph.I.S.I.O. Adult Arterial Filter
COMMON/USUAL NAME:	Arterial Filter
CLASSIFICATION NAME:	Cardiopulmonary Bypass Arterial Line Blood Filter
PREDICATE DEVICE:	Dideco Micro 40 Adult Arterial Filter

DEVICE DESCRIPTION:

The Dideco Micro 40 Ph.I.S.I.O Adult Arterial Filter is an arterial blood filter with a 40 µm screen. The filter is designed to permit the effective separation of gaseous emboli and remove blood components aggregates present in the arterial line. The blood contact surfaces of the arterial filter have been modified to improve blood compatibility.

INDICATIONS FOR USE:

The Dideco Micro 40 Ph.I.S.I.O Adult Arterial Filter is recommended for use in the arterial line of extracorporeal circuit during any procedure that requires cardiopulmonary bypass, for periods up to six hours. The filters are effective in trapping and removing gaseous emboli as well as particulate debris that may be introduced through the arterial line.

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STATEMENT OF TECHNICAL CHARACTERISTICS COMPARISON:

The Dideco Micro 40 Ph.I.S.I.O. Adult Arterial Filter described in this submission is substantially equivalent to the unmodified version, the Dideco Micro 40 Adult Arterial Filter. The devices are identical in design, method of operation, and fundamental scientific technology. Both devices are intended to be used in adult surgical procedures requiring cardiopulmonary bypass for periods up to six hours. The devices differ in that the Dideco Micro 40 Ph.I.S.I.O Adult Arterial Filter contains a surface coating that improves the blood compatibility of the device.

TESTING TO DETERMINE SUBSTANTIAL EQUIVALENCE:

In-vitro tests were performed to demonstrate that the Dideco Micro 40 Ph.I.S.I.O. Adult Arterial Filter described in this submission is substantially equivalent to the unmodified version, the Dideco Micro 40 Adult Arterial Filter.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

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COBE Cardiovascular, Inc.
c/o Ms. Lynne Leonard
Regulatory Affairs, Submission
14401 W. 65th Way
Arvada, CO 80004-3599

Re: K040184
Dideco Micro 40 Adult Arterial Filter
Regulation Number: 21 CFR 870.4260
Regulation Name: Cardiopulmonary Bypass Arterial Line Blood Filter
Regulatory Class: Class II (two)
Product Code: DTM
Dated: January 23, 2004
Received: January 27, 2004

Dear Ms. Leonard:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.
This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (301) 594-4646. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97) you may obtain. Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

Donna R. Vochmel

Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K040184

Device Name: Dideco Micro 40 Ph.I.S.I.O. Adult Arterial Filter

Indications For Use: The Dideco Micro 40 Ph.I.S.I.O. Adult Arterial Filter is recommended for use in the arterial line of extracorporeal circuit during any procedure that requires cardiopulmonary bypass, for periods up to six hours of use. The filters are effective in trapping and removing gaseous emboli as well as particulate debris that may be introduced through the arterial line.

Prescription Use ___X__ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Donna R. Vochmes

(Division Sign-Off)
Division of Cardiovascular Devices

510(K) Number K040184